UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,041	03/14/2000	Daniel R. Soppet	PF178D2	8342

22195 7590 01/07/2004

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	27

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/525,041	Applicant(s) Soppet et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 30, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, and 124* is/are rejected.

7) ☒ Claim(s) *27, 30=-34, 36-37, 53, 56-60, 62-63, 72, 89, 105, 107-112, 114-115* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Amendment filed October 2, 2003 (Paper No. 25) in response to the Office Action of June 30, 2003 (Paper No. 24) is acknowledged and has been entered. Previously pending claims 125-126 have been canceled, claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115, 124 are currently under prosecution.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant points out that Examiner misnumbered the list of pending claims on the previous Office Action Summary, although the pending claims were correctly listed on page 2 of Paper No. 24. Examiner apologizes for any inconvenience.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The specification is objected to and claims 73-76, 78-87, 98-101 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

The claims are drawn to ATCC-97129.

It is unclear if a cell line which produces the molecules of ATCC-97129 is known and publicly available, or can be reproducibly isolated without undue experimentation. Clearly, without access to a cell line which produces the molecules of ATCC-97129, it would not be possible to practice the claimed

invention. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct molecules of the cell line; and/or (3) the claimed cell line molecules amino acid or nucleic acid sequence is an unpredictable event since the specification provides no specific information drawn to the specific cell line.

Applicant has not disclosed the deposit of the cell line, ATCC-97129, nor does the specification provide any nexus between ATCC-97129 and SEQ ID NO:2.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a

patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of the deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

5. Claims 29, 55, 81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29, 55, 81 are indefinite in the recitation of the term "chimeric" antibody. The term is not defined by the specification and the exact meaning of the word chimeric is not known. The term chimeric is generic to a class of antibodies

which are products of genetic shuffling of antibody domains and other active proteins. The term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including but not limited to CDR grafted antibodies.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103, 104, 106, 113, 124 are rejected under 35 U.S.C. § 102(a) and 102(e) as being anticipated by US Patent No. 5,436, 169.

Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103, 104, 106, 113, 124 recite an antibody produced by immunizing an animal. The production of a product by a particular process does not impart novelty or unobviousnes to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685

(CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

It is assumed for examination purposes that ATCC-97129 encodes SEQ ID NO:2.

The claims are drawn to antibodies that bind SEQ ID NO:2.

US Patent No. 5,426,169 teaches a polypeptide, SEQ ID NO: 7 with 7 amino acids identical to those of SEQ ID NO:2, flanked by a single conservatively substituted amino acid and teaches SEQ ID NO:12, the polynucleotide encoding said polypeptide (see us-09-525-041-2.rni, Result 11). The specification further teaches the production of/and claims polyclonal antibodies which bind to said sequence (see claims 1 and 2). Since the encoded protein comprises 7 amino acids, identical to SEQ ID NO:2, which are flanked by a conservatively substituted amino acid, it would be expected that a subset of the polyclonal antibodies that specifically bind to said encoded protein would bind also to SEQ ID NO:2, given that it is understood by those of ordinary skill in the art that the minimum epitope for antibody binding is 5-6 amino acids and that antibodies will bind to epitopes with conservative amino acid substitutions. Although the reference does not specifically

teach that the polyclonal antibodies will bind to SEQ ID NO:2, the claimed antibodies appears to be the same as the prior art antibodies, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

9. Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103, 104, 106, 113, 124 are rejected under 35 U.S.C. § 103 as being unpatentable over Bartoli et al (FEBS Letters, 1993, 327:289-293, also see us-09-525-041-2.rsp, esult 6, attached) in view of US Patent No. 5,436, 169.

Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103, 104, 106, 113, 124 recite an antibody produced by immunizing an animal. The production of a product by a particular process does not impart novelty or unobviousnes to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031,

1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

It is assumed for examination purposes that ATCC-97129 encodes SEQ ID NO:2.

Bartoli et al teach a novel polynucleotide encoding protein regl with homology to reg and the protein encoded thereby (see abstract). Amino acids, residues 98-107 are 80% identical to the corresponding residues of SEQ ID NO:2 and the remaibibg 20% of the ten amino acids are conservative substitutions for the corresponding amino acids of SEQ ID NO:2. The reference teaches as set forth but does not teach polyclonal antibodies to the encoded polypeptide.

US Patent No. 5,436, 169 teaches as set forth above. It is noted that residues 98-107 comprise the eight homologous/conservatively substituted amino acids disclosed forth above in the rejection set forth under 35 USC 102(e).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced polyclonal antibodies against the polypeptide of Bartoli et al because the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). One would have expected to successfully produce said antibodies because US Patent No. 5,436,169 successfully produced antibodies to a sequence with homology to the sequence of Bartoli et al. One would have expected

to successfully produce at least a subset of antibodies that bind to SEQ ID NO:2 given that the encoded protein comprises 10 consecutive amino acids, either identical to/or conservatively substituted of SEQ ID NO:2, given that it is understood by those of ordinary skill in the art that the minimum epitope for antibody binding is 5-6 amino acids and that antibodies will bind to epitopes with conservative amino acid substitutions.

10. No claims allowed.

11. Claims 27, 30-34, 36-37, 53, 56-60, 62-63, 72, 89, 105, 107-112, 114-115 are objected to as dependent upon rejected claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
January 5, 2003

to successfully produce at least a subset of antibodies that bind to SEQ ID NO:2 given that the encoded protein comprises 10 consecutive amino acids, either identical to/or conservatively substituted of SEQ ID NO:2, given that it is understood by those of ordinary skill in the art that the minimum epitope for antibody binding is 5-6 amino acids and that antibodies will bind to epitopes with conservative amino acid substitutions.

10. It is noted that Applicant requests rejoinder of the method claims with the product claims. The claims will not be rejoined because the product claims are not commensurate in scope with the method claims.

11. No claims allowed.

12. Claims 27, 30-34, 36-37, 53, 56-60, 63-63, 72, 89, 105, 107-112, 114-115 are objected to as dependent upon rejected claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
January 5, 2003